DEC 2 1 2011

2 510(k) Summary of Safety and Effectiveness

Date Summary Prepared	November 29, 2011
Manufacturer/Distributor/Sponsor	Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA
510(k) Contact	Courtney Smith Manager, Regulatory Affairs Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA Telephone: 239/643.5553, ext. 1720 Fax: 239/598.5508 Email: csmith@arthrex.com
Trade Name	***Arthrex Fracture System***
Common Name	Plate, fixation, bone
Product Code -Classification Name CFR	HWC, HRS, HTN 21 CFR 888.3030: Single/multiple component metallic bone fixation appliances and accessories 21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener.
Predicate Device	*K011335*: Synthes One-Third Tubular Plates *K102998:* Acumed Congruent Bone Plate System *K043248 / K052776:* Arthrex TightRope Syndesmosis and Acromioclavicular (AC) Devices *K103705 / K111253:* Arthrex Low Profile Screws
Device Description and Intended Use	The ***Arthrex Fracture System*** is a family of stainless steel plates, screws, and buttons. The plates may be contoured or straight and may be available in left and right configurations. The plates are to be used with the 2.7mm-4.0mm Low Profile Screws. The screws are solid and fully threaded and may be locking or non-locking. The button is stainless steel and designed to fit securely in the holes of the fracture plates. The button is intended to be used with the previously cleared suture, which is provided separately. The **Arthrex** ***Fracture System*** is intended to be used for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneous, femur and fibula. The Arthrex Fracture Plates are to be used with the 2.7mm-4.0mm Arthrex Low Profile Screws. The ***Clavicle Plate Button*** is intended for use with the clavicle

	plates for clavicle indications such as for the treatment of syndesmotic trauma, such as fixation of acromioclavicular separations due to coracoclavicular ligament disruption, and this button may not be used alone. The button is intended to be used with #5 FiberWire or FiberTape.
Substantial Equivalence Summary	The Arthrex Fracture System is substantially equivalent to the predicate Synthes One-Third Tubular Plates (K011335), Acumed Congruent Bone Plate System (K102998), Arthrex TightRope Syndesmosis and Acromioclavicular (AC) Devices (K043248 / K052776), and the cleared Arthrex Low Profile Screws (K103705, K111253) in which the basic features and intended uses are the same. Any differences between the ***Fracture System*** and the predicates are considered minor and do not raise questions concerning safety and effectiveness. The proposed devices are composed of Stainless Steel which is substantially equivalent to the predicate devices. The submitted mechanical testing data demonstrated that the bending and pull-out strength of the proposed devices are substantially equivalent to the bending and pull-out strength of the predicate devices. Based on the indication for use, technological characteristics, and the comparison to the predicate devices, Arthrex, Inc. has determined that the ***Fracture System*** is substantially equivalent to currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Arthrex, Incorporated
% Ms. Courtney Smith
Manager, Regulatory Affairs
1370 Creekside Boulevard
Naples, Florida 34108

DEC 2 1 2011

Re: K112437
Trade/Device Name: Arthrex Fracture System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HTN, HWC, HRS
Dated: December 12, 2011
Received: December 14, 2011

Dear Ms. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

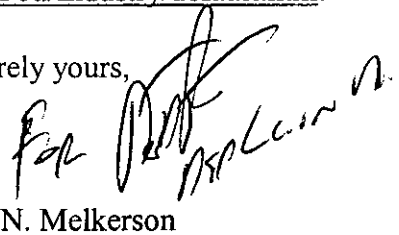
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1 Indications for Use Form

Indications for Use

510(k) Number (if known): K112437

Device Name: *Arthrex Fracture System*

Indications For Use:

The **Arthrex** ***Fracture System*** is intended to be used for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneous, femur and fibula. The Arthrex Fracture Plates are to be used with the 2.7mm-4.0mm Arthrex Low Profile Screws.

The ***Clavicle Plate Button*** is intended for use with the clavicle plates for clavicle indications such as for the treatment of syndesmotic trauma, such as fixation of acromioclavicular separations due to coracoclavicular ligament disruption, and this button may not be used alone. The button is intended to be used with #5 FiberWire or FiberTape.

Prescription Use _✓_ AND/OR Over-The-Counter Use _____

(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for _____
(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K112437